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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,180	02/26/2004	Catherine C. Turkel	17679 (BOT)	9912

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
02/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,180	TURKEL ET AL.	
	Examiner	Art Unit	
	VANESSA L. FORD	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 June 2004* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's request for continued examination filed February 7, 2007 has been entered. Applicant's amendment filed July 17, 2008 has been entered. Claims 1-20 and 29 are under examination. Claims 21-28 have been canceled.

Rejections Maintained

2. The rejection under 35 U.S.C. 101, provisional double patenting is maintained for claims 1, 9-10, 13-19 and 29 for the reasons set forth on pages 3-4 paragraph 4 of the Final Office Action.

The following rejections are maintained and reiterated below:

Provisional Double Patenting

The rejection was on the grounds that the claims are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1-3, 5-12 and 14-17 of copending Application No. 11/039, 506 filed January 18, 2005. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets claims (claims 1, 9-10, 13-19 and 29 of this application and claims 1-17 of copending Application No. 11/039, 506) are drawn to a method of treating medication overuse patients by administering botulinum toxin to the patients. It should be noted that "triptan medication overuse patients" would be a species of the genus "medication overuse patients". Therefore, the scope of the claims 1, 9-10, 13-19 and 29 of this application would encompass the scope of claims 1-3, 5-12 and 14-17 of copending Application No. 11/039, 506.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's Arguments

Applicant urges that they will respond to this rejection when it ripens.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed February 7, 2007 and July 17, 2008 have been fully considered but they are not persuasive. Independent claims 1 is directed to a method for treating an acute pain medication overuse disorder caused by overuse of acute pain medication, the method comprising a step of local administration of a botulinum toxin to a patient with acute pain medication overuse associated with overuse of acute pain medication, wherein the patient takes the medication prior to experiencing pain and experiences pain after the in take of acute pain medication, thereby treating the acute pain medication overuse disorder caused by the overuse of acute pain medication. However, claim 10 depends from claim 1 which is directed wherein the acute pain medication overuse disorder is medication overuse headache, and the administration of the botulinum toxin is effective in reducing the number of headaches experienced by the patient. Co-pending application 11/039,506, independent claims 1 is directed to a method for treating a headache in a triptan medication overuse patient, the method comprising the step of local administration of about 1 to 1500 units of botulinum toxin to a patient who is a triptan medication overuse patient, wherein the patient ingests triptan medication of at least ten days a month and at least twice a week, thereby both

countering a headache exacerbation caused by triptan medication overuse and reducing the use of triptan medication by the patient to treat the headache.

It is known in the art that medication overuse patients ingests at least triptan (acute pain medication) drugs at least ten days per month and at least twice a week. See *Cephalalgia, An International Journal of Headache*, Volume 24, Supplement 1, 2004 (*Cephalalgia, 2004*), which teaches that the most common migraine-like headache occurs on ≥ 15 days per month and occur as a mixture of migraine-like and tension-like headaches (page 94). *Cephalalgia, 2004* teach that these patients overuse migraine drugs and /or analgesics (page 94). *Cephalalgia, 2004* teach that diagnostic criterion used for these patients is ≥ 10 days per month of drug use, this translates into 2-3 treatment days a week (page 94). Based on the teaching of *Cephalalgia, 2004,* a patient that has a diagnostic criterion of ≥ 10 days per month and 2-3 treatment days is considered a “medication-overuse headache patient". Thus, the current claims and claims 1-3, 5-12 and 14-17 of co-pending application 10/789,180 overlap in scope. This the provisional double patenting rejection is maintained.

It is noted that *Cephalalgia, an International Journal of Headache*, Volume 24, Supplement 1, 2004 is only used to provide the state of the prior art.

In view of all of the above, this rejection is maintained.

3. The rejection under 35 U.S.C. 102(a) is maintained for claims 1-3, 10-17, 19-20 and 29 for the reasons set forth on page 4-6, paragraph 5 of the Final Office Action.

The rejection was on the grounds that Schim teaches a method of treating medication overuse disorder by administering to a patient botulinum toxin (page 51). Schim teaches this method because Schim teaches that botulinum toxin was administered to patients with and without analgesic overuse (Study 3, page 51). Schim teaches that botulinum toxin was effective in treating patients with medication overuse disorder (page 51).

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that the claims 1, 9 and 16 have been amended to recite "the patient takes medication prior to experiencing pain". Applicant urges that the present claims are directed to the preemptive use of medication not necessarily associated with an actual pain or ache.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed February 7, 2007 and July 17, 2008 have been fully considered but they are not persuasive.

Schim teaches administering botulinum toxin patients that have acute medication overuse disorder (these patients misuse acute pain medication such as triptans) (see case study 3, page 51). It should be noted that Schim teaches that the populations of patients used in the studies used acute medication before and after botulinum toxin

treatment (page 50, 2nd column). Schim teaches that the patients used in the study are medication overusers. Applicant has provided no evidence that the acute medication overuse disorder described in the prior art is not caused by medication overuse.

To address Applicant comments regarding claim 29, the skilled artisan would reasonable conclude that Schim teaches all limitations of claim 29 because the patients used in the studies of Schim are analgesic medication overusers and as set forth on page 9 of Applicant's specification the International Headache Society define medication overuse as person that experiences a chronic headache frequency greater than 15 days per month after the intake of analgesics or ergots more than 15 times per month for at least 3 months. See also *Cephalalgia, 2004.*

In view of all of the above, this rejection is maintained.

4. The rejection under 35 U.S.C. 102(b) is maintained for claims 1-20 and 29 for the reasons set forth on pages 6-8, paragraph 6 of the previous Office Action.

The rejection was on the grounds that Tepper et al teach a method of treating medication overuse disorder by administering to a patient botulinum toxin (page 715). Tepper et al teach that the patients were administered 100 units of botulinum toxin A (page 715). Tepper et al teach that botulinum toxin was effective in treating patients with medication overuse disorder (page 715).

Applicant's Arguments

Applicant urges that the claims 1, 9 and 16 have been amended to recite "the patient takes medication prior to experiencing pain". Applicant urges that the present claims are directed to the preemptive use of medication not necessarily associated with an actual pain or ache.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed February 7, 2007 and July 17, 2008 have been fully considered but they are not persuasive. Tepper et al teach administering botulinum toxin patients that have acute medication overuse disorder (these patients misuse acute pain medication) (see Abstract). It should be noted that Tepper et al teach that botulinum toxin therapy reduces the use of pain medication as well as reduces the frequency of pain, intensity of pain, days with severe headache and headache intensity (Abstract). Tepper et al teach that acute medication overuse patients that have been given botulinum therapy experience headaches (pain) after the intake of acute pain medication. Therefore, Tepper et al teach that the patients used in the study are medication overusers. Applicant has provided no evidence that the acute medication overuse disorder described in the prior art is not caused by medication overuse.

To address Applicant comments regarding claim 29, the skilled artisan would reasonable conclude that Tepper et al teach all limitations of claim 29 because the patients used in the studies of Tepper et al are analgesic medication overusers and as

set forth on page 9 of Applicant's specification the International Headache Society define medication overuse as person that experiences a chronic headache frequency greater than 15 days per month after the intake of analgesics or ergots more than 15 times per month for at least 3 months. See also *Cephalalgia, 2004.*

In view of all of the above, this rejection is maintained.

5. The rejection under 35 U.S.C. 102(b) is maintained for claims 1-20 and 29 for the reasons set forth on pages 8-9, paragraph 7 of the Final Office Action.

Matthew et al teach a method of treating medication overuse disorder by administering to a patient botulinum toxin (see the Abstract). Mathew et al teach that the patients with and without analgesic overuse were administered 50 to 100 units of botulinum toxin A to multiple scalp and neck sites (see the Abstract). Matthew et al teach that botulinum toxin was effective in treating patients with medication overuse by reducing the number of chronic migraine and thereby reducing the acute medication use (see the Abstract).

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that Matthew et al do not teach or suggest treatment of an acute pain medication overuse disorder wherein the pain experienced by the patient is caused by overuse of acute pain medication. Applicant urges that there is no teaching or suggestion in Matthew et al that the headaches suffered by the patients were caused by the intake of medication but rather that some patients had analgesic overuse.

Applicant urges that Matthew et al is direct at treating chronic migraine and not overuse medication overuse. Applicant urges that the claims have been amended to include the limitation wherein the patient experiences pain after intake of acute pain medication.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed February 7, 2007 and July 17, 2008 have been fully considered but they are not persuasive. Matthew et al teach administering botulinum toxin patients that have acute medication overuse disorder (these patients misuse acute pain medication) (see Abstract). It should be noted that patient in the study had high acute medication overuse in spite of detoxification from analgesics. Thus, Matthew et al teach that acute medication overuse patients that have been given and appropriate prophylactic therapy botulinum therapy experience headaches prior to and after the intake of acute pain medication. Matthew et al teach that the patients used in the study are medication overusers. Applicant has provided no evidence that the acute medication overuse disorder described in the prior art is not caused by medication overuse.

To address Applicant comments regarding claim 29, the skilled artisan would reasonable conclude that Mathew et al teach all limitations of claim 29 because the patients used in the studies of Matthew et al are analgesic medication overusers and as set forth on page 9 of Applicant's specification the International Headache Society define medication overuse as person that experiences a chronic headache frequency greater than 15 days per month after the intake of analgesics or ergots more than 15 times per month for at least 3 months. See also *Cephalalgia, 2004.*

In view of all of the above, this rejection is maintained.

Status of Claims

6. No claims allowed.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANESSA L. FORD whose telephone number is (571)272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/
Examiner, Art Unit 1645
February 9, 2009